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PATENT, TRADEMARK, COPYRIGHT  
AND UNFAIR COMPETITION LAW  
AND RELATED LITIGATION

EDMUND P. WOOD 1923-1988  
TRUMAN A. HERRON 1935-1976  
EDWARD B. EVANS 1936-1971

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**FACSIMILE COVER SHEET**

To: Art Unit: 3732  
Examiner: Anu Ramana

Fax: 703-872-9306

From: David E. Jefferies

Re: Serial No: 09/765,151  
Filed: January 17, 2001  
Applicant: Gilbert R. Gonzales et al.  
COMBINATION AND METHOD  
INCLUDING A VISUAL MARKER  
FOR DETERMINING COMPLIANCE  
WITH A MEDICATION REGIMEN  
Art Unit: 3732  
Examiner: Anu Ramana  
Attorney Docket: UNSP-04 (now  
PEDI-27)

Pages: 2 (including cover sheet)

**MESSAGE/COMMENTS**

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Application Serial No. 09/765,151  
Amendment dated March 18, 2005  
Reply to Office Action dated November 18, 2004

cosmetic characteristic (color) to the composition, much like a flavoring agent would be used to make the composition more palatable. There is no teaching in Pather that such coloring agents function as anything but as a superficial component for aesthetic and cosmetic purposes. Again, these are essentially optional components with respect to the therapeutic action provided by the composition. The Pather references does not inherently disclose utilizing a marker in a form and sufficient amount to cause coloration of a patient cavity enabling subsequent visual observation.

Applicants submit that the use of coloring agents as optional components in Pather is very apparent when one considers the disclosure of column 5, lines 1-6 when taken in view of the paragraph at column 4, lines 52-58 of Pather. The paragraph concerning coloring at column 5, lines 1-6 is introduced earlier in the paragraph of column 4, lines 52-58 as a mere list of ingredients which may be included in the composition. These ingredients may include "glidants, lubricants, binders, sweetener, flavoring, and coloring components." The subsequent paragraphs go on to simply list examples of these coloring ingredients. However, there is no indication that the coloring agent plays any significant role in the composition of Pather, nor does Pather teach that the coloring agent is present in a form and amount sufficient to stain the oral and/or pharyngeal cavity for subsequent visual observation to determine compliance with a medication regimen. In contrast, the coloring agent of the composition of the present application is what allows an observer to determine compliance, duration since